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09/674,546	11/04/2002	Claire Fraser	PP00365.301	9020

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EXAMINER	
DEVI, SARVAMANGALA J N	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/674,546	FRASER ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4 and 19-32* is/are pending in the application.

4a) Of the above claim(s) *2 and 19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11807 & 92506*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicants' amendments filed 11/04/02, 05/13/03, 07/17/03 and 05/09/06.

Election of Species

2) Acknowledgment is made of Applicants' election filed 04/02/07 in response to the species election requirement mailed 02/20/07. Applicants have elected, with traverse, the polypeptide fragment species comprising 10 or more consecutive amino acids from SEQ ID NO: 2536. The Applicants' traversal is on the grounds that the restriction practice in this national stage application is governed by PCT Rule 13 as set forth in 37 CFR 1.475 and that all three sets of claims include the polypeptide defined by the amino acid sequence of SEQ ID NO: 2536 as 'a special technical feature' since each of the independent claims read upon this amino acid sequence. Applicants cite section 1850 of MPEP and state that to require restriction between three independent claims directed to overlapping sets of polypeptides which have the common special technical feature of the polypeptide having the amino acid sequence of SEQ ID NO: 2536 seems to be very narrow or literal approach which the MPEP indicates is not allowed. Applicants submit that even under the arguably narrower rules applied to 35 U.S.C § 111 patent application, the restriction would be improper as there would be no undue burden on the searching.

Applicants' arguments have been carefully considered, but are not persuasive. The Office Action mailed 02/20/07 was a species election requirement as opposed to a restriction requirement. The three independent claims were not restricted. The identified polypeptide species encompass a number of oligomeric fragments of SEQ ID NO: 2536, polypeptide variants of SEQ ID NO: 2536, and polypeptide variants of a specific fragment of SEQ ID NO: 2536. Because of the open claim language 'comprising', the amino acid residues on either side of any decameric fragment of SEQ ID NO: 2536 and the amino acid residues on either side of the 19-274 residue fragment from SEQ ID NO: 2536 can be any residues other than those that are present on either side of amino acids 19-274 within SEQ ID NO: 2536 and on either side of amino acids any decameric fragment of SEQ ID NO: 2536. Therefore, the structures of the identified species are mutually exclusive. Additionally, there is examination *burden* involving the written description and the enablement issues associated with

the multiple variants of SEQ ID NO: 2536 and variants of 19-274 residue fragment from SEQ ID NO: 2536 currently claimed. As set forth below in the Office Action, the identification alone of claims from Applicants' multiple co-pending applications that encompass the claimed polypeptide species, polypeptide fragments species, and polypeptide variant species in order to determine double patenting issues following extensive review of the sequence search reports is just one example that establishes an examination burden. Therefore, the species election requirement held in the instant application is proper and is hereby maintained.

Status of Claims

3) Claims 1, 3 and 5-18 have been canceled via the amendment filed 01/16/2007.

Claims 2 and 4 have been amended via the amendment filed 01/16/2007.

New claims 19-32 have been added via the amendment filed 01/16/2007.

Claims 2, 4 and 19-32 are pending.

Claims 2, 19-21 and 29-32 have been withdrawn from consideration as being directed to a non-elected species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 4 and 22-28 are under prosecution. A First Action on the Merits is issued for these claims.

Information Disclosure Statements

4) Acknowledgment is made of Applicants' information disclosure statements filed 01/18/07 and 09/25/06. The information referred to therein has been considered and a signed copy of the same is attached to this Office Action.

Sequence Listing

5) Acknowledgment is made of Applicants' sequence listing which has been entered on 05/15/06.

Priority

6) This application is a national stage application filed under 35 U.S.C § 371 application of PCT/US99/09346 filed 04/30/1999 and claims priority to the U.S provisional applications 60103749, filed 10/09/1998, 60099062 filed 09/02/1998, 60098994 filed 09/02/1998, 60098869 filed 07/31/1998, and 60083758 filed 05/01/1998.

REQUIREMENT FOR INFORMATION UNDER 37 C.F.R 1.105

7) Applicants and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the Office has determined is reasonably necessary to properly examine of this application or treat matter in one or more pending applications filed under 35 U.S.C 111 or 35 U.S.C 371.

In response to this requirement, please identify all the pending applications filed by at least by one of the inventors, or assigned to the same assignee as the current application which disclose the subject matter or the overlapping subject encompassed within the scope of the instant claims 2, 4 and 19-32 that are not otherwise identified in the current application, so that a determination can be made on double patenting issues.

It appears that Applicants are prosecuting multiple applications that encompass the subject matter claimed in the instant claims. A reasonable number of pending applications currently being prosecuted and the relevant claims therefrom that include double patenting issues have been identified below under 'Double Patenting' rejections. Applicants should identify the rest of the applications that are being prosecuted.

Applicants are reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Under 37 C.F.R § 1.56 Applicant has the duty to disclose to the Office all information known to be material to patentability of the claimed subject matter including those identified above.

This requirement is a part of the enclosed Office Action. A complete reply to the enclosed Office Action must include a complete reply to this requirement. The time period for this requirement coincides with the time period for reply to the enclosed Office Action.

Specification

8) The instant specification is objected to for the following reasons:

(a) Figure 1 is missing in the set of drawings (30/30 pages) filed 11/01/00.

(b) The drawings for Figures 2 through 7 and Figure 9 comprise five panels, A-E. The drawings for Figures 8 and 23 comprise four panels. The drawing for Figure 19 has three panels. The drawings for Figures 20, 21 and 22 include two panels. Yet, the section 'Brief Description of Drawings' on pages 3-5 of the specification does not identify these Figures, for example as, --Fig.

2A-2E--, Fig. 23A-23D etc. Appropriate correction is needed.

(c) The sequences depicted in Figures 19-23 and pages 69-71 of the instant specification are not identified by specific SEQ ID numbers as required under 37 C.F.R 1.821 through 1.825. Any sequences recited in the instant specification, which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825. Note that branched sequences are specifically excluded from this definition.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g).

(d) The use of trademark recitations in the instant specification has been noted. For example, see 'Span 85', 'Tween 80' and 'pluronic' on page 35; see 'Sarkosyl' on page 53; see 'Sepharose' on pages 60, 61 and 63; see 'Tween 20' on page 66; and see 'Triton X 100' on page 68 of the instant specification. The recitations should be capitalized wherever they appear. See M.P.E.P 608.01(V) and Appendix l. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to trademark recitations, wherever such recitations appear.

(e) The ATCC address provided in the second full paragraph of page 38 and first full paragraph of page 40 of the specification is incorrect. Effective 23 March 1998, ATCC has a new address: 10801 University Boulevard, Manassas, VA 20110-2209. Amendment to the specification is suggested to reflect this. It is suggested that Applicants examine the whole specification to make similar correction to the address, wherever it appears.

(f) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See the third full paragraph on page 53 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Double Patenting Rejection(s)

9) The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10) Claims 4 and 22-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5-7, 10 and 11 of the co-pending application 11395121. Although the conflicting claims are not identical, they are not patentably distinct from each other, because the above-identified claims of the co-pending application, drawn to an isolated immunogenic polypeptide having SEQ ID NO: 18, and a vaccine comprising the same and a pharmaceutically effective carrier, are encompassed within the scope of the instant claims. The polypeptide sequence of SEQ ID NO: 18, as claimed in the co-pending application, has 100% sequence identity with the instantly recited SEQ ID NO: 2536, and therefore is expected to comprise an at least ten amino acid-long fragment of the instantly recited SEQ ID NO: 2536 therein. Although the claims of the co-pending application do not expressly recite that the immunogenic polypeptide is purified, it is viewed as a polypeptide that is purified at least to some degree since the polypeptide is contained in the claimed vaccine that is meant for *in vivo* use. Alternatively, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to further purify the patent application's polypeptide comprising SEQ ID NO: 18 for the purpose of providing a more pure composition since purified immunogenic polypeptide compositions are ideally desired in the art for *in vivo* administration.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

11) Claims 4, 22-26 and 28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 8, 21 and 29 of the co-pending application 10530753. Although the conflicting claims are not identical, they are not patentably distinct from each other, because the above-identified claims of the co-pending application, drawn to a polypeptide composition that induces bactericidal antibody response after administration to a subject wherein the polypeptide comprises SEQ ID NO: 3 or SEQ ID NO: 8, is encompassed within the scope of the instant claims. The polypeptide sequence of SEQ ID NO: 3 or 8, as claimed in the co-pending application has at least 90% sequence identity with the instantly recited SEQ ID NO: 2536, and therefore is expected to comprise an at least ten amino acid-long fragment of the instantly recited SEQ ID NO: 2536 therein. Although the claims of the co-pending application do not expressly recite that the polypeptide is purified, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to further purify the patent application's polypeptide comprising SEQ ID NO: 3 or 8 for the expected benefit of providing a more pure composition since purified polypeptide compositions are ideally desired in the art for *in vivo* administration.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

12) Claims 4, 22-26 and 28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11 and 13 of the co-pending application 10536215. Although the conflicting claims are not identical, the claims are not patentably distinct from each other, because the above identified claims of the co-pending application, drawn to a protein antigen composition comprising one or more of proteins having the amino acid sequence of SEQ ID NO: 139, 79, 80, 82, 83, 85 and 142, wherein the composition can elicit a bactericidal antibody response, is encompassed within the scope of the instant claims. The one or more amino acid sequences of SEQ ID NO: 139, 79, 80, 82, 83, 85 and 142 of the protein composition as claimed in the co-pending application have at least 90% sequence identity with the instantly recited SEQ ID NO: 2536, and therefore are expected to comprise an at least ten amino

acid-long fragment of the instantly recited SEQ ID NO: 2536 therein. Although the claims of the co-pending application do not expressly recite that the proteins are purified, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to further purify the patent application's protein composition comprising SEQ ID NO: 139, 79, 80, 82, 83, 85 and 142 for the expected benefit of providing a more pure composition, since purified protein compositions are ideally desired in the art for *in vivo* administration to elicit a bactericidal response.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

13) Claims 4 and 22-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 15, 18 and 20 of the co-pending application 10488786. Although the conflicting claims are not identical, they are not patentably distinct from each other, because the above identified claims of the co-pending application, drawn to a protein and a composition comprising the protein and a pharmaceutically acceptable carrier, wherein the protein comprises an amino acid sequence of SEQ ID NO: 2, 6, 8, 11, 12 or 30, is encompassed within the scope of the instant claims. The protein comprising an amino acid sequence of SEQ ID NO: 2, 6, 8, 11, 12 or 30 as claimed in the co-pending application has at least 90% sequence identity with the instantly recited SEQ ID NO: 2536 and therefore is expected to comprise an at least ten amino acid-long fragment of the instantly recited SEQ ID NO: 2536 therein. Although the claims of the co-pending application do not expressly recite that the polypeptide is purified, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to further purify the patent application's polypeptide composition comprising SEQ ID NO: 2, 6, 8, 11, 12 or 30 for the expected benefit of providing said protein composition in a much purified form, since purified polypeptide compositions are ideally desired in the art for *in vivo* administration to elicit a bactericidal response.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

14) Claim 28 is rejected and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. This is a new matter rejection.

The new claim 28 includes the limitation: 'purified polypeptide of claim 4, wherein said peptide is immunogenic'. Applicants point to original claims 16-18 and state that these original claims provide support for the new claim 28. However, the claimed polypeptide comprising a fragment of SEQ ID NO: 2536 wherein the fragment is 10 or more consecutive amino acids from said SEQ ID NO: 2536, wherein the 'peptide' is 'immunogenic' as claimed in claim 28 is not supported by the original claims 16-18, because these original claims do not describe a 10 amino acid-long or larger polypeptide comprising a fragment of SEQ ID NO: 2536 wherein the peptide is immunogenic. Therefore, the above-identified limitation in the claim is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

15) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

16) Claim 28 is rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 28 is indefinite because these claims have improper antecedence in the limitation 'said peptide'. Claim 28 depends from claim 4, which does not recite any 'peptide'.

Remarks

17) Claims 4 and 21-28 stand rejected.

18) This Office Action has an attached requirement for information under 37 CFR 1.105. A complete reply to this Office action must include a complete reply to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

19) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

20) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

21) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

June, 2007

S. DEVI, PH.D.
PRIMARY EXAMINER

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER